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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/791,290	03/03/2004	Frank S. D'Amelio SR.	45437	3540
1609 7590 05/28/2009 ROYLANCE, ABRAMS, BERDO & GOODMAN, L.L.P. 1300 19TH STREET, N.W. SUITE 600 WASHINGTON,, DC 20036				
EXAMINER				
ROBERTS, LEZAH				
ART UNIT		PAPER NUMBER		
1612				
MAIL DATE		DELIVERY MODE		
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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

# Office Action Summary

**Application No.**

10/791,290

**Applicant(s)**

D'AMELIO ET AL.

**Examiner**

LEZAH W. ROBERTS

**Art Unit**

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 04 February 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-3, 7, 9-13, 16, 22, 24-26 and 29 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 10 and 26 is/are allowed.
- 6) ☒ Claim(s) 1-3, 7, 9, 11-13, 16, 22, 24, 25 and 29 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

## **DETAILED ACTION**

Applicants' arguments, filed February 4, 2009, have been fully considered. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

### ***Claims***

#### **Claim Rejections - 35 USC § 112 – New Matter (New Rejections)**

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 12, 13, 22, 24, 25 and 29 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

1) The claims recite the limitation "consisting essentially of". This limitation does not appear to be disclosed or recited in the originally filed specification or claims.

2) Claims 12 and 22 recite the limitation an antiseptic agent including chlorophyll, peppermint oil, cinnamon bark oil, prickly ash bark extract, calendula extract, Echinacea extract, chamomile extract, olive leaf extract, black walnut hull extract, grapefruit seed extract, and green tea extract. These components do not appear to be disclosed as antiseptic agents or components of an antiseptic agent in the originally filed specification or claims.

**Claim Rejections - 35 USC § 103 – Obviousness (Previous Rejection)**

1) Claims 1, 9 and 11 were rejected under 35 U.S.C. 103(a) as being unpatentable over Romanowski et al (US 2005/0158252). The rejection is maintained.

**Applicant's Arguments**

Applicants previously submitted a Declaration Under 37 C.F.R. § 1.131 to swear back of the effective date of Romanowski et al. that shows conception and reduction to practice of the oral composition as claimed prior to the effective date of Romanowski et al. The evidence presented with the Declaration specifically shows conception of each of the components recited in claim 1, thus establishing a date of invention prior to the effective date of Romanowski et al. The law does not require that the claim be recited

verbatim in the evidence in a Declaration and evidence relied on is not required to show only what is recited in the claims.

Applicant argues it would not have been obvious to one skilled in the art in view of Romanowski et al. to combine the claimed components in the specific amounts as recited in claim 1 for inhibiting the growth of oral bacteria and to inhibit inflammation of oral tissue as in claim 1. The Action provides no basis or rationale for the position that it would have been obvious to select and combine the randomly disclosed components of Romanowski et al. in the manner of the claimed invention.

Applicant further argues Romanowski et al. does not disclose a holistic extract of Centipeda as in the claimed invention and the specification defines the meaning of a holistic extract and discloses a method for obtaining the holistic extract. Thus, the specification defines the claimed holistic extract of the Centipeda genus in a manner not suggested by Romanowski et al.

Applicants further assert that the enhanced performance of the claimed composition is obtained by the specific combination. For example, the bio-saponin is a natural surfactant which breaks down the outer layer of cells and other waxy layers which enables the gota kola to function more effectively to promote lysis of bacteria, enhances the performance of other components such as the Centipeda extract, coenzyme Q10, aloe vera, folic acid and Vitamin E. Romanowski et al. does not disclose or suggest the function of the components, and thus, provides no suggestion to one skilled in the art to combine the components in the manner of the claimed invention.

Examiner's Response

In regards to the Declaration, the composition disclosed in the Declaration does not comprise vitamin E, which appears to be an active agent in the instant invention and also recited in the independent claims. Considering the component is an active agent and would alter the properties of the composition, the Declaration does not provide support for this limitation. Thus the Declaration is insufficient to overcome Romanowski et al.

In regards to holistic extract, Applicant discloses a holistic extract can be obtained by various methods. It is also submitted that the resulting extract is a holistic mixture of active components in "substantially the same ratio" as the active components that are present in the native plant material. The term "substantially" is not defined and it cannot be ascertained what constitutes "substantially the same ratio". Further, it appears the "holistic extract" may be obtained by any of the solvent disclosed by the instant specification, which discloses a suitable polar, nonpolar, semi-polar or mixtures thereof, thus it appears that any extract that is obtained by any one of the numerous solvent would be a "holistic extract".

In regards to the combination of components, as asserted before by the Examiner, it is *prima facie* obviousness to select a known material based on its suitability for its intended use and the ingredients in the claims are disclosed by Romanowski et al. as agents that kill microorganisms, reduce inflammation and rebuild damaged tissue. Inflammation is what Applicant appears to assert is a major function of the recited compositions. Therefore Romanowski suggests the function of the

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components. Therefore it would have been obvious to combine these components for their functional value. The suggestion for adding the components together is the recitation that the components may be included into the compositions in mixtures. Each component has a specific function and therefore it would be obvious to combine the components to obtain a composition with the particular functions. Although Applicant has reasserted that bio-saponin provides the compositions with enhanced activity due to its mechanism of action on the cells, Applicant has not shown any evidence of this action to support this assertion as suggested in the previous office action dated January 11, 2008, page 4. Furthermore Applicant does not recite the effective amount in which bio-saponin is needed to achieve the asserted function. The instant claims, in particular the independent claim 1, read on a broad amount of bio-saponin.

2) Claims 1-3, 7, 9, 11-13, 16, 17, 22, 24, 25 and 28-33 were rejected under 35 U.S.C. 103(a) as being unpatentable over Close (US 2002/0044977) in view of Harrison (The Periodontal Solution: Healthy Gums Naturally) and Rice et al. (US 5,741,138). The rejection is maintained.

#### Applicant's Arguments

Applicant argues Close does not suggest to one skilled in the art a composition containing the claimed holistic extract of Centipeda in combination with the coenzyme

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Q10, aloe vera, folic acid, Vitamin E, gota kola, bio-saponin, thyme oil and olive leaf as in claim 1. Harrison and Rice et al. provide no suggestion to one skilled in the art to combine the components in the manner of the claimed invention. The Action provides no reasonable rationale for the position that it would have been obvious to combine the components in the manner of the claimed invention. The claimed combination of components is based on experimentation to provide anti-inflammatory properties for treating oral tissue and provide a moisturizing feel to the mouth while being effective in inhibiting inflammation and inhibiting the growth of oral bacteria. In contrast, the compositions of Close, Harrison and Rice et al. typically exhibit an astringent or drying feel to the mouth. One skilled in the art would not have been motivated to select the specific components of Close, Harrison and Rice et al. and combine the components in the manner of the claimed invention with a reasonable expectation of success in inhibiting the growth of oral bacteria and inhibiting inflammation of oral tissue.

The combination of the cited patents does not suggest to one skilled in the art an antiseptic agent consisting essentially of the recited components either alone or in combination with the extract of Centipeda, coenzyme Q10, folic acid and aloe vera in the amounts recited in independent claims 12 and 22.

#### Examiner's Response

As mentioned above, Applicant discloses a holistic extract can be obtained by various methods. It is also submitted that the resulting extract is a holistic mixture of active components in "substantially the same ratio" as the active components that are



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present in the native plant material. The term "substantially" is not defined and it cannot be ascertained what constitutes "substantially the same ratio". Further, it appears the "holistic extract" may be obtained by any of the solvent disclosed by the instant specification, which discloses a suitable polar, nonpolar, semi-polar or mixtures thereof, thus it appears that any extract that is obtained by any one of the numerous solvent would be a "holistic extract". Further, Close discloses the extract is obtained from an aqueous alcoholic extract, therefore encompassing "holistic" as described by Applicant's instant disclosure. The reference also suggests incorporating abrasives, solvents, humectants, detergents, binders, herbal actives (e.g. aloe vera), essential oils (e.g. eucalyptus oil, peppermint oil), deodorizing agents (e.g. chlorophyll) and/or suspension agents (e.g. hydrogenated castor oil). The secondary reference provides the functional value of components encompassed by these categories, thereby giving motivation as to why one of ordinary skill in the art would have used these components in conjunction with the compositions of Close. Furthermore it is *prima facie* obviousness to select a known material based on its suitability for its intended use. See MPEP 2144.07, which further supports the instant rejection.

In regards to the negative properties Applicant asserts would result in the combination of Close, Harrison and Rice et al., Applicant does not appear to provide support for his assertion. Further the combination would lead one of skill in the art to the compositions of the instant claims and therefore would reasonably expect the compositions to provide a moisturizing feel to the mouth while being effective in inhibiting inflammation and inhibiting the growth of oral bacteria.

### ***Allowable Subject Matter***

Claims 10 and 26 are allowable as presently advised.

### ***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP

§ 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to LEZAH W. ROBERTS whose telephone number is (571)272-1071. The examiner can normally be reached on 8:30 - 5:00.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Frederick F. Krass can be reached on 571-272-0580. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Lezah W Roberts/  
Examiner, Art Unit 1612

/Frederick Krass/  
Supervisory Patent Examiner, Art Unit 1612